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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,565	12/21/2001	Oscar M. Bassinson	6739	9996

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REINHART BOERNER VAN DEUREN S.C.
ATTN: LINDA GABRIEL, DOCKET COORDINATOR
1000 NORTH WATER STREET
SUITE 2100
MILWAUKEE, WI 53202

EXAMINER

JOYNES, ROBERT M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 12/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,565

Applicant(s)

BASSINSON, OSCAR M.

Examiner

Robert M. Joynes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicants' Amendment and Response filed on September 22, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellstrom alone or in combination with BE 637363A. Hellstrom teaches an individualized pharmaceutical package comprising a relatively rigid backing member with a depression therein and an item for dispensing positioned with a central depressed area of said backing member and a membrane stretched over the item and joined at the periphery of the backing member (Col. 5, lines 46-60; Col. 6, lines 9-18; Col. 14, Claims 1 & 2). The reference teaches that the item included in the package can be a tablet, capsule, pill, liquid, semiliquid or powder (Col. 5, lines 46-60; Col. 8,

lines 51-75). The liquids, semiliquids and powder are contained in a cup attached to the backing member (Col. 8, lines 51-75). Hellstrom does not limit the active agents that can be administered with such a package system.

Hellstrom does not expressly teach that the powder formulation is absorbed onto the backing member with the use of a binding agent. Hellstrom further does not expressly teach the exact active agents recited in the instant claims to be administered from the package. Hellstrom further does not teach that the backing member is in the size and shape of a credit card.

It is the position of the Examiner that the particular active agent to be dispensed with said package system is not critical. In addition, the size and shape of the backing member also does not appear to be critical. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to dispense various active agent from a package system such as described by Hellstrom wherein the size and shape of the backing member is varied. One would be motivated to vary the drug to be dispensed to prepare different individualized packages for the various drugs or actives that one would need to carry with them. In addition, one would vary the size and shape of backing member for aesthetic reasons as well as for convenience, depending upon the form of the active agent. It is the position of the Examiner that these are limitations that would be routinely determined by one of ordinary skill in the art through minimal experimentation, as being suitable, absent the presentation of some unusual and/or unexpected results. The results must be those that accrue from the specific limitations.

Further, it is the position of the Examiner that the attaching of the powder directly to the card with a binding agent is also not critical. The prior art teaches various forms of the package system that include tablets, or capsule or powders. The Examiner sees no criticality in binding the drug directly to backing member. The prior art appears to teach the same general concept of the package system – a backing member, an active formulation and a film covering the active formulation. The prior art provides a package that is easily transported and provides easy administration of the formulation contained within the package.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to vary the form of the active composition that is contained within the package of the Hellstrom. One of ordinary skill would be motivated to do so to most effectively deliver the desired active agent to the host.

Therefore, the instant claims are rendered obvious over the prior art absent a clear showing of unusual or unexpected results. The results must be those that accrue from the specific limitations.

In addition, Hellstrom can be combined with BE 637363 A (hereinafter '363) reference. The teachings of Hellstrom are discussed above. Hellstrom does not expressly teach that the active agent is attached to the backing member with a binding agent.

'363 teaches a medicament composition in which an active agent is absorbed or attached to inert fiber of paper with a water-soluble binding agent (See abstract). The

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paper product can be provided in the form of a stamp or in other convenient forms so that any dose may be conveniently administered.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach an active agent with a binding agent to a backing member made from paper to administer a desired drug.

One would have been motivated to do so to reduce research time and research costs in developing a tablet or capsule formulation.

Again, it is the position of the Examiner that the particular active agent to be dispensed with said package system is not critical. In addition, the size and shape of the backing member also does not appear to be critical. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to dispense various active agent from a package system such as described by Hellstrom wherein the size and shape of the backing member is varied.

One would be motivated to vary the drug to be dispensed to prepare different individualized packages for the various drugs or actives that one would need to carry with them. In addition, one would vary the size and shape of backing member for aesthetic reasons as well as for convenience, depending upon the form of the active agent. It is the position of the Examiner that these are limitations that would be routinely determined by one of ordinary skill in the art through minimal experimentation, as being suitable, absent the presentation of some unusual and/or unexpected results. The results must be those that accrue from the specific limitations.

Therefore, the instant claims are rendered obvious over Hellstrom in combination with '363.

Response to Arguments

Applicant's arguments filed September 22, 2003 have been fully considered but they are not persuasive. Applicants argue that the prior art fails to teach or suggest a medication card on which a medication is contained or coated directly on to a surface of a base, applied directly to a surface of a base or otherwise retained by the backing member alone. Further, applicants argue that no removable cover is taught by the primary reference and that the art teaches away from such a cover. Still further, applicants argue that the prior art teaches a different method of using the card to dispense the medication contained therein.

In response, the Examiner would first like to state that the claims are given the broadest possible interpretation when examined. The broadest independent claims recite a card-like base form, a surface upon which the card is in contact with the medication composition and a cover that is defined as removable.

To compare this interpretation of the claims with the prior art, Hellstrom, as stated above, teaches a card base that contains a recess or a cup for containing the medication composition on one side of the card. Further, the reference teaches that a cover or membrane is placed on the base to cover the medication composition. The art teaches a card-like base that can have a recess or a cup to contain the medication. This is the surface upon which the medication is to be contained. The broadest independent claims do not recite that the medication composition is directly adhered to

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the card surface. Rather, the claims recite that the card-like base must have a surface to contain the medication. The prior art teaches such a surface in two embodiments, the recessed area or the cup. Therefore, the art teaches such a limitation.

As for the removable cover, the composition taught by the prior art, by its nature, must include a removable cover because the medication must be dispensed from the card. The instant claims recite no limitation with regard to how the cover is removed or to what extent the cover is removed. If the cover was not removable in the prior art the medication would not be dispensed. The art teaches a cover, whether it is broken or peeled off is of little importance in a composition claim. The cover is on the card-like base and is removed in some fashion, whether it is broken or peeled off, to expose the medication to the patient. Therefore, the cover must be removable for the medication to be dispensed.

As for the method of delivering a medication, the prior art teaches that the card is formed with purpose of dispensing the medication contained therein to the patient. At column 3, lines 12-16, the reference states that the composition to be dispensed can be dispensed directly into the patient's mouth. When this teaching is taken in consideration with the above comments, the Examiner fails to see the difference in the method of delivering the medication. As stated above, the prior art teaches or suggests the limitations of the broadest interpretation of the instant claims and teaches that the device can be used to dispense the medication directly into the patient's mouth.

The rejections recited in the Office Action dated May 21, 2003 is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
December 11, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600